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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,346

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Yoshiki Sawa

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,346	<b>Applicant(s)</b> SAWA ET AL.	
	<b>Examiner</b> TERRA C. GIBBS	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>December 23, 2005</u> .                                       | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-8 are pending in the instant application.

Claims 1-8 have been examined on the merits.

### ***Information Disclosure Statement***

Applicant's information disclosure statement filed December 23, 2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Drawings***

The drawings filed on March 15, 2005 are acknowledged. The drawings are objected to because the description of the drawings indicates that such material may very well be critical to determining whether there exists adequate description and enablement of the instant invention. In brief, Figure 2 is sufficiently poor enough that it is difficult to determine what is actually being described. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the

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drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 824 918 (submitted as reference AA on Applicant's Information Disclosure filed December 23, 2005).

Claim 1 is drawn to a method for regulating transcription activated by the transcription factor NF $\kappa$ B in a part of a blood vessel or vascular graft, wherein the method comprises the step of contacting the graft with a decoy for the transcription factor NF $\kappa$ B. Claims 2, 3, and 5 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations wherein part of the vessel or vascular graft is a vein graft; wherein the method comprises contacting the NF $\kappa$ B decoy with a part of the vessel or vascular graft *in vivo* or *ex vivo*; and wherein the method suppresses neointimal formation in the graft by contact with the decoy against the transcription factor NF $\kappa$ B. Claim 6 is drawn to an agent for protection from intimal thickening in a vascular graft, wherein the agent comprises a NF $\kappa$ B decoy. Claim 7 is dependent on claim 6 and includes all the limitations of claim 6 with the further limitation wherein the vascular graft is a vein graft.

EP 0 824 918 discloses and claims a method for the therapy and prophylaxis of NF $\kappa$ B-associated diseases, the method comprising administering an effective amount of an NF $\kappa$ B decoy to a mammal (see claims 10 and 17, for example). EP 0 824 918 also discloses and claims a composition for the therapy and prophylaxis of NF $\kappa$ B-associated diseases, the composition comprising a NF $\kappa$ B decoy (see claim 1, for example). EP 0 824 918 discloses that the NF $\kappa$ B decoy composition is administered to blood vessels and graft material.

Therefore, EP 0 824 918 anticipates claims 1-3 and 5-7.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/11687 A1.

The claims are as described above.

WO 95/11687 discloses and claims a method of modulating gene transcription *in vivo* within mammalian cells, the method comprising administering a NF $\kappa$ B decoy (see claims 1 and 6, for example). WO 95/11687 also discloses and claims a method for treating a mammalian host to prevent restenosis, the method comprising administering a NF $\kappa$ B decoy (see claim 8, for example). WO 95/11687 discloses and claims a composition comprising a NF $\kappa$ B decoy (see claims 9 and 11, for example). WO 95/11687 discloses that the NF $\kappa$ B decoy are used to modulate gene expression and regulate intimal hyperplasia (see Abstract, for example).

Therefore, WO 95/11687 anticipates claims 1-3 and 5-7.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Feely et al. (Transplantation, 2000 Vol. 70:1560-1568, submitted as reference AC on Applicant's Information Disclosure filed December 23, 2005).

Claims 1-3 and 5-7 are as described above. Claim 4 is dependent on claim 1 and includes all the limitations of claim 1 with the further limitation wherein the method comprises introducing the NF $\kappa$ B decoy into the vessel or vascular graft using a pressure-mediated method. Claim 8 is dependent on claim 6 and includes all the

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limitations of claim 6 with the further limitation wherein the agent is for introducing an NF $\kappa$ B decoy into a vessel or vascular graft using a pressure-mediated method.

Feely et al. disclose an *ex vivo* method for inhibiting graft coronary artery disease after cardiac transplantation in a mammal, the method comprising administering a NF $\kappa$ B decoy (see Abstract and Table 4, for example). Specifically, Feely et al. disclose the administration of a NF $\kappa$ B decoy to adult male rats using a pressure-mediated delivery, specifically hyperbaric pressure (see page 1561, first and second columns, for example).

Therefore, Feely et al. anticipate claims 1-8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either EP 0 824 918 (submitted as reference AA on Applicant's Information Disclosure filed December 23, 2005) or WO 95/11687 A1, in view of Mann et al. (The Lancet, 1999 Vol. 354:1493-141498, submitted as reference AE on Applicant's Information Disclosure filed December 23, 2005).

Claim 1 is drawn to a method for regulating transcription activated by the transcription factor NF $\kappa$ B in a part of a blood vessel or vascular graft, wherein the method comprises the step of contacting the graft with a decoy for the transcription factor NF $\kappa$ B. Claims 2-5 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations wherein part of the vessel or vascular graft is a vein graft; wherein the method comprises contacting the NF $\kappa$ B decoy with a part of the vessel or vascular graft *in vivo* or *ex vivo*; wherein the method comprises introducing the NF $\kappa$ B decoy into the vessel or vascular graft using a pressure-mediated method; and wherein the method suppresses neointimal formation in the graft by contact with the decoy against the transcription factor NF $\kappa$ B. Claim 6 is drawn to an agent for protection from intimal thickening in a vascular graft, wherein the agent comprises a NF $\kappa$ B decoy. Claims 7 and 8 are dependent on claim 6 and include all the limitations of claim 6 with

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the further limitations wherein the vascular graft is a vein graft; and wherein the agent is for introducing an NF $\kappa$ B decoy into a vessel or vascular graft using a pressure-mediated method.

*Determining the scope and contents of the prior art*

EP 0 824 918 teaches and claims a method for the therapy and prophylaxis of NF $\kappa$ B-associated diseases which comprises administering an effective amount of an NF $\kappa$ B decoy to a mammal (see claims 10 and 17, for example). EP 0 824 918 also teaches and claims a composition for the therapy and prophylaxis of NF $\kappa$ B-associated diseases which comprises a NF $\kappa$ B decoy (see claim 1, for example). EP 0 824 918 teaches that the NF $\kappa$ B decoy composition is administered to blood vessels and graft material.

WO 95/11687 teaches and claims a method of modulating gene transcription *in vivo* within mammalian cells, the method comprising administering a NF $\kappa$ B decoy (see claims 1 and 6, for example). WO 95/11687 also teaches and claims a method for treating a mammalian host to prevent restenosis, the method comprising administering a NF $\kappa$ B decoy (see claim 8, for example). WO 95/11687 teaches and claims a composition comprising a NF $\kappa$ B decoy (see claims 9 and 11, for example). WO 95/11687 teaches that the NF $\kappa$ B decoy are used to modulate gene expression and regulate intimal hyperplasia (see Abstract, for example).

*Ascertaining the differences between the prior art and the claims at issue*

Neither EP 0 824 918 nor WO 95/11687 teach introducing an NF $\kappa$ B decoy into a

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vessel or vascular graft using a pressure-mediated method.

Mann et al. teach introducing decoys into human vein grafts using a pressure-mediated method (see Abstract, for example). Specifically, Mann et al. teach that an application using a pressure-mediated method strategy may lower failure rates of human primary bypass vein grafting.

*Resolving the level of ordinary skill in the pertinent art*

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

*Considering objective evidence present in the application indicating obviousness or nonobviousness*

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to devise a method for regulating transcription activated by the transcription factor NF $\kappa$ B in a part of a blood vessel or vascular graft, wherein the method comprises the step of contacting the graft with a decoy for the transcription factor NF $\kappa$ B using the teachings of either EP 0 824 918 or WO 95/11687. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to introduce the NF $\kappa$ B decoy using a pressure-mediated method using the teachings and motivation of Mann et al.

One of ordinary skill in the art would have been motivated to devise a method for regulating transcription activated by the transcription factor NF $\kappa$ B in a part of a blood vessel or vascular graft, wherein the method comprises the step of contacting the graft with a decoy for the transcription factor NF $\kappa$ B since both EP 0 824 918 and WO

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95/11687 taught that such a method could treat NF $\kappa$ B-associated diseases. One of ordinary skill in the art would have been motivated to introduce the NF $\kappa$ B decoy using a pressure-mediated method since Mann et al. taught that such a delivery method offers a promising approach for the prevention of coronary and peripheral bypass failure in mammals.

One of ordinary skill in the art would have had a reasonable expectation of success of devising a method for regulating transcription activated by the transcription factor NF $\kappa$ B in a part of a blood vessel or vascular graft, wherein the method comprises the step of contacting the graft with a decoy for the transcription factor NF $\kappa$ B since both EP 0 824 918 and WO 95/11687 taught the successful use and design of such a method. One of ordinary skill in the art would have had a reasonable expectation of success of introducing the decoy using a pressure-mediated method since Mann et al. taught the successful use and design of such a delivery method *in vivo*.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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December 12, 2008  
/Terra Cotta Gibbs/